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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,398	02/27/2004	Kathleen M. Miller	98-P0151US2	4925

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EXAMINER	
SWEET, THOMAS	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
06/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,398	MILLER ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) *1-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 16, filed 03/11/2008, with respect to double patenting have been fully considered and are persuasive. The rejections of claims 73-74, 76-77, 80-82, 84, and 86 has been withdrawn.

Applicant's arguments, see page 19-20 and 22-23, filed 03/11/2008, with respect to rejections based on Pinchuk et al have been fully considered and are persuasive. The rejections of claims 73-94 have been withdrawn. Regarding claims 80 and 89, applicant did not challenge the Examiners official notice regarding lubricious hydrophilic coatings being well known in the art of ureteral stents which is now admitted prior art. Regarding claims 81, applicant did not challenge the Examiners official notice regarding the use of plural apertures in the walls of a stent being well known in the art of ureteral stents which is now admitted prior art. Regarding claims 82, 83 and 88, applicant did not challenge the Examiners official notice regarding bismuth subcarbonate as a radio-opacifying agent being well known in the art of ureteral stents which is now admitted prior art. Regarding claims 86 and 94, applicant did not challenge the Examiners official notice regarding end regions of different durometer valve being well known in the art of ureteral stents which is now admitted prior art. Regarding claims 85 and 87, applicant did not challenge the Examiners official notice regarding wall thickness in the .2-.8mm range being well known in the art of ureteral stents which is now admitted prior art.

Applicant's arguments, see page 20-22, filed 03/11/2008, with respect to rejection based on Bucay-Couto et al have been fully considered and are persuasive. The rejection of claims 73-74, 76-77 and 84 has been withdrawn.

Applicant did not respond to the 103 rejection of claims 80, 81 and 86 based on Bucay-Couto et al.

Applicant's arguments with respect to claims 73-74, 76-77, 80 and 82 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 98 recites the broad recitation acrylcarboxylic acid, and the claim also recites clidanac, ketorolac, or tinoridine which is the narrower statement of the range/limitation.

Claims 96, 98, and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Applicant is claiming alternatives but not in the accepted Markush format of "selected from the group consisting of " a, b, c "and" d.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 75, 80, 89, 95-97 and 103 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Modak et al (US 6224579 from the IDS).. Modak et al discloses a ureteral stent (col 4, lines 16-36) comprising a polymeric tubular shaft, said polymeric tubular shaft comprising a matrix polymer comprising, an antimicrobial agent (triclosan, title),and a microbial attachment/biofilm synthesis inhibitor (Ag EDTA, col 4, lines 3-14).

Regarding claim 75, see col 4 line 45-.1-20% triclosan.

Regarding claims 80 and 89, lubricous surface col 15, lines 404-45.

Regarding claims 97-99, "a silver compound, "(Ag EDTA) "and an anti-inflammatory agent" (salicylic acid, col 10, lines 18-21)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 84 and 90 are rejected under 35 U.S.C. 102(a or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Modak et al. The resulting structure is the same there fore Modak et al is fully capable of having been melt-extruded.

Claims 81-88 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al.

Regarding claims 81, obviousness of use of plural apertures in the walls of a urethral stent is now admitted prior art.

Regarding claims 82, 83 and 88, obviousness of bismuth subcarbonate as a radio-opacifying agent in the art of ureteral stents is now admitted prior art.

Regarding claims 86 and 94, obviousness of end regions of different durometer valve in the art of ureteral stents is now admitted prior art.

Regarding claims 85 and 87, obviousness of wall thickness in the .2-.8mm range in the art of ureteral stents is now admitted prior art.

Claims 76-79 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view of Schwarz et al (US 2001/0022988). Modak et al discloses a stent as discussed above. However, Modak et al does not disclose use of ethylene vinyl acetate copolymer. Schwarz et al discloses another stent using ethylene vinyl acetate copolymer for the purpose of holding drugs for local delivery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ethylene vinyl acetate copolymer of Schwarz et al for the drug polymer of Modak et al in order to locally deliver drug. Such a

modification amounts to mere substitution of one functionally equivalent drug polymer for another within the art of stents.

Regarding claims 78-79, It is a matter of mere design choice to vary the percentages of drug to polymer which is not patentably distinct from the prior art.

Regarding claims 91-93, the 5-20 wt % triclosan and EVA ureteral stent as rejected above is structurally identical and therefore would function the same as the claimed stent.

Claims 100-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view of Buscemi et al (US 5693034). Modak et al discloses a stent as discussed above including use of suitable hydrophilic polymer as a lubricant (col 10, lines 14-17). However, Modak et al remain silent as to the suitable hydrophilic polymer being polyacrylic acid. Buscemi et al teaches another lubricant of hydrophilic polymer using polyacrylic acid for the purpose of lubricating medical devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polyacrylic acid coating of Buscemi et al as the lubricous coating of Modak et al in order to lubricate the medical device. Such a modification amounts to mere substitution of one functionally equivalent lubrication coating for another within the art of medical devices.

Claims 102 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al in view of Schwarz et al (US 2001/0022988) and further in view of Falk et al. (US 6048844). Modak et al discloses a stent as discussed above. However, Modak et al does not disclose the use of ketorolac as an anti-inflammatory. Falk et al. discloses another stent using ketorolac for the purpose of functioning as an anti-inflammatory. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ketorolac as

taught by Falk et al for the salicylic acid of Modak et al in order to function as an anti-inflammatory. Such a modification amounts to mere substitution of one functionally equivalent anti-inflammatory for another within the art of stents.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/
Primary Examiner, Art Unit 3774